

## § 1311.60

that the registrant is allowed to order and invalidate any order that includes substances the registrant is not allowed to order.

(10) The system must ensure that an invalid finding cannot be bypassed or ignored and the order filled.

(11) The system must archive the order and associate with it the digital certificate received with the order.

(12) If a registrant sends reports on orders to DEA, the system must create a report in the format DEA specifies, as provided in § 1305.29 of this chapter.

(d) For systems used to process CSOS orders, the system developer or vendor must have an initial independent third-party audit of the system and an additional independent third-party audit whenever the signing or verifying functionality is changed to determine whether it correctly performs the functions listed under paragraphs (b) and (c) of this section. The system developer must retain the most recent audit results and retain the results of any other audits of the software completed within the previous two years.

### § 1311.60 Recordkeeping.

(a) A supplier and purchaser must maintain records of CSOS electronic orders and any linked records for two years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records.

(b) Electronic records must be easily readable or easily rendered into a format that a person can read. They must be made available to the Administration upon request.

(c) CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.

## Subpart C—Electronic Prescriptions

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### § 1311.100 General.

(a) This subpart addresses the requirements that must be met to issue and process Schedule II, III, IV, and V

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controlled substance prescriptions electronically.

(b) A practitioner may issue a prescription for a Schedule II, III, IV, or V controlled substance electronically if all of the following conditions are met:

(1) The practitioner is registered as an individual practitioner or exempt from the requirement of registration under part 1301 of this chapter and is authorized under the registration or exemption to dispense the controlled substance;

(2) The practitioner uses an electronic prescription application that meets all of the applicable requirements of this subpart; and

(3) The prescription is otherwise in conformity with the requirements of the Act and this chapter.

(c) An electronic prescription for a Schedule II, III, IV, or V controlled substance created using an electronic prescription application that does not meet the requirements of this subpart is not a valid prescription, as that term is defined in § 1300.03 of this chapter.

(d) A controlled substance prescription created using an electronic prescription application that meets the requirements of this subpart is not a valid prescription if any of the functions required under this subpart were disabled when the prescription was indicated as ready for signature and signed.

(e) A registered pharmacy may process electronic prescriptions for controlled substances only if all of the following conditions are met:

(1) The pharmacy uses a pharmacy application that meets all of the applicable requirements of this subpart; and

(2) The prescription is otherwise in conformity with the requirements of the Act and this chapter.

(f) Nothing in this part alters the responsibilities of the practitioner and pharmacy, specified in part 1306 of this chapter, to ensure the validity of a controlled substance prescription.

### § 1311.102 Practitioner responsibilities.

(a) The practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other

person. The practitioner must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. Failure by the practitioner to secure the hard token, knowledge factor, or biometric information may provide a basis for revocation or suspension of registration pursuant to section 304(a)(4) of the Act (21 U.S.C. 824(a)(4)).

(b) The practitioner must notify the individuals designated under § 1311.125 or § 1311.130 within one business day of discovery that the hard token has been lost, stolen, or compromised or the authentication protocol has been otherwise compromised. A practitioner who fails to comply with this provision may be held responsible for any controlled substance prescriptions written using his two-factor authentication credential.

(c) If the practitioner is notified by an intermediary or pharmacy that an electronic prescription was not successfully delivered, as provided in § 1311.170, he must ensure that any paper or oral prescription (where permitted) issued as a replacement of the original electronic prescription indicates that the prescription was originally transmitted electronically to a particular pharmacy and that the transmission failed.

(d) Before initially using an electronic prescription application to sign and transmit controlled substance prescriptions, the practitioner must determine that the third-party auditor or certification organization has found that the electronic prescription application records, stores, and transmits the following accurately and consistently:

(1) The information required for a prescription under § 1306.05(a) of this chapter.

(2) The indication of signing as required by § 1311.120(b)(17) or the digital signature created by the practitioner's private key.

(3) The number of refills as required by § 1306.22 of this chapter.

(e) If the third-party auditor or certification organization has found that an electronic prescription application does not accurately and consistently record, store, and transmit other infor-

mation required for prescriptions under this chapter, the practitioner must not create, sign, and transmit electronic prescriptions for controlled substances that are subject to the additional information requirements.

(f) The practitioner must not use the electronic prescription application to sign and transmit electronic controlled substance prescriptions if any of the functions of the application required by this subpart have been disabled or appear to be functioning improperly.

(g) If an electronic prescription application provider notifies an individual practitioner that a third-party audit or certification report indicates that the application or the application provider no longer meets the requirements of this part or notifies him that the application provider has identified an issue that makes the application non-compliant, the practitioner must do the following:

(1) Immediately cease to issue electronic controlled substance prescriptions using the application.

(2) Ensure, for an installed electronic prescription application at an individual practitioner's practice, that the individuals designated under § 1311.125 terminate access for signing controlled substance prescriptions.

(h) If an electronic prescription application provider notifies an institutional practitioner that a third-party audit or certification report indicates that the application or the application provider no longer meets the requirements of this part or notifies it that the application provider has identified an issue that makes the application non-compliant, the institutional practitioner must ensure that the individuals designated under § 1311.130 terminate access for signing controlled substance prescriptions.

(i) An individual practitioner or institutional practitioner that receives a notification that the electronic prescription application is not in compliance with the requirements of this part must not use the application to issue electronic controlled substance prescriptions until it is notified that the application is again compliant and all relevant updates to the application have been installed.

(j) The practitioner must notify both the individuals designated under § 1311.125 or § 1311.130 and the Administration within one business day of discovery that one or more prescriptions that were issued under a DEA registration held by that practitioner were prescriptions the practitioner had not signed or were not consistent with the prescriptions he signed.

(k) The practitioner has the same responsibilities when issuing prescriptions for controlled substances via electronic means as when issuing a paper or oral prescription. Nothing in this subpart relieves a practitioner of his responsibility to dispense controlled substances only for a legitimate medical purpose while acting in the usual course of his professional practice. If an agent enters information at the practitioner's direction prior to the practitioner reviewing and approving the information and signing and authorizing the transmission of that information, the practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.

**§ 1311.105 Requirements for obtaining an authentication credential—Individual practitioners.**

(a) An individual practitioner must obtain a two-factor authentication credential from one of the following:

(1) A credential service provider that has been approved by the General Services Administration Office of Technology Strategy/Division of Identity Management to conduct identity proofing that meets the requirements of Assurance Level 3 or above as specified in NIST SP 800-63-1 as incorporated by reference in § 1311.08.

(2) For digital certificates, a certification authority that is cross-certified with the Federal Bridge certification authority and that operates at a Federal Bridge Certification Authority basic assurance level or above.

(b) The practitioner must submit identity proofing information to the credential service provider or certification authority as specified by the credential service provider or certification authority.

(c) The credential service provider or certification authority must issue the

authentication credential using two channels (e.g., e-mail, mail, or telephone call). If one of the factors used in the authentication protocol is a biometric, or if the practitioner has a hard token that is being enabled to sign controlled substances prescriptions, the credential service provider or certification authority must issue two pieces of information used to generate or activate the authentication credential using two channels.

**§ 1311.110 Requirements for obtaining an authentication credential—Individual practitioners eligible to use an electronic prescription application of an institutional practitioner.**

(a) For any registrant or person exempted from the requirement of registration under § 1301.22(c) of this chapter who is eligible to use the institutional practitioner's electronic prescription application to sign prescriptions for controlled substances, the entity within a DEA-registered institutional practitioner that grants that individual practitioner privileges at the institutional practitioner (e.g., a hospital credentialing office) may conduct identity proofing and authorize the issuance of the authentication credential. That entity must do the following:

(1) Ensure that photographic identification issued by the Federal Government or a State government matches the person presenting the identification.

(2) Ensure that the individual practitioner's State authorization to practice and, where applicable, State authorization to prescribe controlled substances, is current and in good standing.

(3) Either ensure that the individual practitioner's DEA registration is current and in good standing or ensure that the institutional practitioner has granted the individual practitioner exempt from the requirement of registration under § 1301.22 of this chapter privileges to prescribe controlled substances using the institutional practitioner's DEA registration number.

(4) If the individual practitioner is an employee of a health care facility that is operated by the Department of Veterans Affairs, confirm that the individual practitioner has been duly appointed to practice at that facility by the Secretary of the Department of